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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,253 | 01/26/2005 | Samuel Weiss | 16601-021US1 | 8661 |

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| EXAMINER | |
|---|---|
| TON, THAIAN N | |
| ART UNIT | PAPER NUMBER |
| 1632 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 05/28/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/523,253 | WEISS, SAMUEL | |
| | Examiner | Art Unit | |
| | Thaian N. Ton | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,6-9 and 41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-9 and 41-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/09;3/27/09;11/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Examiner of Record is now Thaian N. Ton of Art Unit 1632.

Applicants' Amendment and Remarks, mailed 9/17/08, have been entered. Claims 41-50 are newly added; claims 1, 6-9, 41-50 are pending and under current examination.

### *Information Disclosure Statement*

Applicants' IDS, filed 3/20/09, 3/27/09 and 11/7/08 have been considered.

### *Claim Rejections - 35 USC § 112*

The prior rejection of claims 1, 6-9 under 35 U.S.C. 112, first paragraph, enablement, is withdrawn in view of Applicants' amendment to the claims which now recite utilizing GM-CSF.

### *Written Description*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-9 and newly added claims 41-50 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

*Applicants' Arguments.* Applicants argue that the claims have now been amended to recite that GM-CSF is selected from various mammalian species, and that claim 1, as amended sets forth a limited genus that is described by the spec.

Additionally, Applicants argue that newly added claim 41 recites that GM-CSF is at least 80% identical to human GM-CSF, and that the sequence for human GM-CSF is well know, and that general knowledge in the art and aid of a computer would have put one of skill in the art in possession of the genus of sequences that have 80% sequence identity to human GM-CSF. Applicants argue similarly for claim 46, which recites that the GM-CSF is at least 80% identical to mouse GM-CSF. See pages 7-8 of the Response.

*Response to Arguments*. These arguments have been fully considered, but are not persuasive. In particular, although one of skill in the art would recognize that the GM-CSF sequence is well known for many species, what lacks written description in the instant case is that the specification defines "granulocyte-macrophage colony stimulating factor" as any protein that shares at least 30% identity with the native human GM-CSF, and possesses a biological activity of the native human GM-CSF, which it binds to any known GM-CSF. Therefore, this encompasses a large genus of fragments and variants of GM-CSF that have not been described by the specification. Additionally, although one of skill in the art would recognize proteins that were at least 80% identical to human or mouse GM-CSF, it would not be readily apparent given the teachings of the specification, which of these proteins would have the required function of producing oligodendrocytes from multipotent neural stem cells. Although GM-CSF from a number of different species have already been identified in the prior art, relative to the claimed genus of polypeptides, it is only a small subset of the claimed polypeptides which is not a representative number of species that satisfies the entire genus. Accordingly, it is maintained that the claimed invention lacks written description.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. ..[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to

one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claim 1 recites contacting the multipotent neural stem cell with "granulocyte-macrophage colony stimulating factor." The specification defines "granulocyte-macrophage colony stimulating factor" as any protein that shares at least 30% identity with the native human GM-CSF, and possesses a biological activity of the native human GM-CSF, which it binds to any known GM-CSF receptor (see page 11, lines 17-19, and page 12, lines 10-11). The claimed genus of GM-CSF encompasses a large number of polypeptides that may or may not have the biological function of stimulating neural stem cell proliferation and differentiation into oligodendrocytes. Although GM-CSF from a number of different species have already been identified in the prior art, relative to the claimed genus of polypeptides, it is only a small subset of the claimed polypeptides which is not a representative number of species that satisfied the entire genus. The specification only demonstrates the murine GM-CSF induces oliogodendrocyte differentiation in a mouse neural stem cell. The specification does not any other polypeptide comprises 30% sequence identity to human GM-CSF (any polypeptide that comprises 44 amino acid identical to human GM-CSF sequence) which can bind to

any GM-CSF receptor that possesses the same function. The specification fails to describe critical fragment of the human GM-CSF which is required for the function of induce oligodendrocyte lineage commitment. As such, the specification fails to provide sufficient description to the claimed invention to reasonably convey one of skilled in the art that the inventor had possession of the invention at the time the invention was made.

## *Conclusion*

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632